510K SUMMARY

K022613

Submitted By: ERBE USA, Inc.
2225 Northwest Parkway
Marietta, GA 30067

Tel: 770-955-4400
Fax: 770-955-2577

OCT 2 5 2002

Contact Person: John Tartal

Date Prepared: 08/05/02

Common Name: Water Jet Dissector

Trade/Proprietary Name: Helix Hydro-Jet™

Classification Name: Jet Lavage (21CFR880.5475)

Product Code: FQH

Legally Marketed Device: Helix Hydro-Jet

Note: This 510(k) is being submitted to modestly expand the intended use for the Helix Hydro-Jet. There are three additional applicators in this 510(k) that would support the added indications. They were also included in the previous 510(k) [K012464] but were removed when the intended use was limited.

Device Description:

The Helix Hydro-Jet is a hydraulic pressure delivery system that uses physiological saline to cut and dissect soft tissue. A very detail description of the system can be found in the previous 510(k), K012464, Device Description 1-1.

Note: A summary of design control activities, risk analysis, verifications/validations, and biocompatibility can also be found respectively in Sections 4-1, 5-1, 6-1, 9-1, and 8-1 of the previous 510(k). Also, certifications and the declaration of conformity are in the former 510(k) Appendices A and B respectively.

Intended Use*:

The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as laparoscopic surgery.

*Modified 10/18/02 per request by FDA.

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Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

The modified device is the same as the predicate except for a slight expansion of the intended use and the addition of supporting applicators.

The difference to the indication is:

1. Cutting and dissection of soft tissue in the abdomen including Total Mesorectal Excision (TME)* {Change from just using the device in the Abdomen} and

2. Laparoscopic use in treating the target tissue (Change from just using the device in open surgery).

The modest change to the intended use is supported by scientific documentation provided in this Section as apart of Clinical Evaluations (See III-9).

Collectively the added applicators are different in that:

1. One of the applicators has a handle and a flexible tip,

2. The maximum cannula length changed from 300 to 336 mm, and

3. One of the applicators has a hook.

The additional features in having a handle, flexible tip, hook, and/or being slightly longer provide surgeon's applicators that would especially be useful in hard to reach areas as well as for laparoscopic use in or near the abdomen. The applicators have been verified/validated in design control. Risk analysis also has been performed with regards to the features.

Conclusion:

All available/known studies involving the Helix Hydro-Jet and like water jet equipment in conjunction with the expanded intended use have been provided in this submission (Note: An exhaustive literature search was performed.). The clinical documentation provided demonstrates that the Helix Hydro-Jet may be used safely and effectively to cut/dissect soft tissue that is in close proximity of the abdomen [Note: Shown by use in Total Mesorectal Excision (TME)]. The evaluations also show that system can be used in laparoscopic procedures for the target tissues with regards to safety and efficacy. Finally, the modified structural and dimensional features of the added applicators do not adversely affect the safety or effectiveness of the Helix Hydro-Jet.

The use of the Helix Hydro-Jet in TME was found to be better in comparison to other approved equipment. Greater visibility and tissue selectivity with the water jet system

COMPARISON TABLE

Characteristics	Modified Device	Predicate Device
Manufacturer	Andreas Pein Medizintechnik GmbH	Andreas Pein Medizintechnik GmbH
510(k) Applicant	ERBE USA, Inc.*	Andreas Pein Medizintechnik GmbH
Device Name	Water Jet Dissector	Water Jet Dissector
Trade Name	Helix Hydro-Jet™	Helix Hydro-Jet
510(k) Number		K012464
Indications For Use	The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as laparoscopic surgery.	The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue such as the liver and kidney in open abdominal surgery.
Items of the System	Unit, Suction Container, Power Cord, Foot Pedal, Fluid Cartridge, Applicators, and Suction Bag	Unit, Suction Container, Power Cord, Foot Pedal, Fluid Cartridge, Applicators, and Suction Bag
Materials	No Change [See the specific contacting materials in previous 510(k)- K012464, 8-1.]	No Change [See the specific contacting materials in previous 510(k)- K012464, 8-1.]
Physical and Dimensional Attributes		
• Unit, Suction Container, Power Cord, and Foot Pedal (Reusable) as well as Fluid Cartridge, and Suction Bag (Single Use)	No Change [See the physical and dimensional attributes in previous 510(k)- K012464, 1-7 to 1-21.]	No Change [See the physical and dimensional attributes in previous 510(k)- K012464, 1-7 to 1-21.]

COMPARISON TABLE

Characteristics	Modified Device	Predicate Device
• Applicators	With and Without a Handle; With and Without Suction or Suction Control; Straight, Bayonet or Angled Cannula; Cannula Outer Diameter Range: 1.6 to 6 mm; Cannula Length Range: 60 to 336 mm; Sheath: Pliable or Rigid; Tip: Rigid, Flexible, Straight, Curved, and/or Hooked; Delivered Jet Stream: Straight or Spatula Shape	With and Without Suction or Suction Control; Straight , Bayonet, or Angled Cannula; Cannula Outer Diameter Range: 1.6 to 6 mm; Cannula Length Range: 60 to 300 mm; Sheath: Pliable or Rigid; Tip: Straight or Curved; Delivered Jet Stream: Straight or Spatula Shape
Energy Delivered	Pressurized Sterile Saline that Cuts and Dissects	Pressurized Sterile Saline that Cuts and Dissects
Pressure and Suction Ranges as well as Jet Diameter	1 to 2,175 psi; 0 to –11.6 psi; 120 *um*	1 to 2,175 psi; 0 to –11.6 psi; 120 *um*
Target Population	Patients Requiring Open or Laparoscopic Surgery in and around the Abdomen	Patients Requiring Open Abdominal Surgery
Anatomical Sites	Soft Tissue within the Abdomen including TME	Soft Tissue in the Abdomen
Condition Provided and Method of Sterilization As Applicable		
• Unit, Suction Container, Power Cord, Foot Pedal, and Suction Bag	Non-Sterile	Non-Sterile
• Fluid Cartridge	Sterile/Gamma Radiation	Sterile/Gamma Radiation
• Applicator	Sterile/Ethylene Oxide	Sterile/Ethylene Oxide
Use Condition		
• Unit, Suction Container, Power Cord, and Foot Pedal	Reusable	Reusable
• Fluid Cartridge, Applicator, and Suction Bag	Disposable (Single Use)	Disposable (Single Use)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Tartal
Manager, Quality Assurance/Regulatory Affairs
ERBE USA, Inc.
Surgical Systems
2225 Northwest Parkway
Marietta, Georgia 30067

OCT 2 5 2002

Re: K022613
Trade/Device Name: Helix Hydro-Jet™
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH
Dated: August 5, 2002
Received: August 6, 2002

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K022613

DEVICE NAME: Helix Hydro-Jet™

INDICATIONS FOR USE:

The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as laparoscopic surgery.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022613

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER P; IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter- (Optional Forma